

Arnold B. Calmann, Esq.  
Jeffrey Soos, Esq.  
**SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC**  
One Gateway Center, 13<sup>th</sup> Floor  
Newark, New Jersey 07102  
Telephone: (973) 622-3333  
Facsimile: (973) 622-3349

*Of counsel:*  
Barry S. White, Esq.  
Steven M. Amundson, Esq.  
Dillon Kim, Esq.  
**FROMMER LAWRENCE & HAUG LLP**  
745 Fifth Avenue  
New York, New York 10151  
Telephone: (212) 588-0800  
Facsimile: (212) 588-0500

*Attorneys for Defendants,  
Lupin Limited and Lupin Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

---

**TEVA PHARMACEUTICAL INDUSTRIES  
LTD. and TEVA PHARMACEUTICALS  
USA, INC.,**

**Plaintiffs,**

**v.**

**LUPIN LIMITED and LUPIN  
PHARMACEUTICALS, INC.,**

**Defendants.**

---

**Civil Action No. 07-247 (WHW) (RJH)**

***Document Electronically Filed***

**DEFENDANTS' ANSWER AND COUNTERCLAIM**

Defendants, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively “Lupin”), by their attorneys, respond to the averments made in the numbered paragraphs of the Complaint filed by Plaintiffs, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively “Teva”), as follows:

Complaint Paragraph 1: Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

Answer: Lupin admits the allegations in paragraph 1.

Complaint Paragraph 2: Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

Answer: Lupin admits the allegations in paragraph 2.

Complaint Paragraph 3: On information and belief, Lupin Limited is an Indian corporation having a principal place of business at Laxmi Towers, “B” Wing, 5th Floor, Bandra Kurla Complex, Mumbai - 400 051, India.

Answer: Lupin admits the allegations in paragraph 3.

Complaint Paragraph 4: On information and belief, Lupin Pharmaceuticals, Inc. is a Virginia corporation having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202.

Answer: Lupin admits the allegations in paragraph 4.

Complaint Paragraph 5: On information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey, and has designated National Registered Agents, Inc. at Suite 108, 100 Canal Pointe Blvd., Princeton, NJ for receipt of service.

Answer: Lupin admits the allegations in paragraph 5.

Complaint Paragraph 6: On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Limited.

Answer: Lupin admits the allegations in paragraph 6.

Complaint Paragraph 7: On information and belief, Lupin Pharmaceuticals, Inc. acts as the agent of Lupin Limited. Lupin Limited and Lupin Pharmaceuticals, Inc. collectively will be referred to hereafter as “Defendants.”

Answer: Lupin denies the allegations contained in the first sentence in paragraph 7 but admits the allegations contained in the second sentence in paragraph 7.

Complaint Paragraph 8: This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 281-285.

Answer: With respect to paragraph 8, Lupin admits that Teva purports to bring this action under Title 35, United States Code. Lupin denies the remaining allegations in paragraph 8, and expressly denies any infringement and that Teva is entitled to any relief.

Complaint Paragraph 9: This court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Answer: With respect to paragraph 9 of the complaint, Lupin only admits that Teva purports to base jurisdiction on 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Complaint Paragraph 10: This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court’s jurisdiction.

Answer: Lupin admits the allegations in paragraph 10.

Complaint Paragraph 11: The Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because of its continuous and systematic contacts with the state of New Jersey.

Answer: Lupin Pharmaceuticals, Inc. denies the allegations in paragraph 11, but Lupin Pharmaceuticals, Inc. will not contest personal jurisdiction in New Jersey for the limited purposes of this action.

Complaint Paragraph 12: The Court has personal jurisdiction over Lupin Limited because of its continuous and systematic contacts with the state of New Jersey, including those made through Lupin Pharmaceuticals, Inc.

Answer: Lupin Limited denies the allegations in paragraph 12, but Lupin Limited will not contest personal jurisdiction in New Jersey for the limited purposes of this action.

Complaint Paragraph 13: Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c) and (d).

Answer: Lupin denies the allegations in paragraph 14, but Lupin will not contest venue in this judicial district for the limited purposes of this action.

Complaint Paragraph 14: Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,600,073 (“the ’073 patent”), 6,500,987 (“the ’987 patent”), 6,495,721 (“the ’721 patent”), and 6,897,340 (“the ’340 patent”) (collectively, “the patents in suit”) relating to, inter alia, methods for manufacturing certain crystalline forms of a chemical compound known as sertraline hydrochloride. Two of these crystalline forms of sertraline hydrochloride are known as “Form II” and “Form V.”

Answer: With respect to paragraph 14 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in its present form, but to the extent Lupin understands said allegations and without waiver of the foregoing, Lupin admits only that (a) Teva Pharmaceutical Industries Ltd. is listed as the assignee of all of the patents in suit; (b) the title of the '721 patent is "Sertraline Hydrochloride Form II and Methods for the Preparation Thereof"; (c) the title of the '987 patent is "Sertraline Hydrochloride Polymorphs"; (d) the title of the '073 patent is "Methods for Preparation of Sertraline Hydrochloride Polymorphs"; and (e) the title of the '340 patent is "Processes for Preparation of Polymorphic Form II of Sertraline Hydrochloride." Lupin denies the remaining allegations in paragraph 14.

Complaint Paragraph 15: The '073 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on July 29, 2003 for an invention entitled "Methods for Preparation of Sertraline Hydrochloride Polymorphs." A copy of the '073 patent is attached as Exhibit A.

Answer: With respect to paragraph 15 of the complaint, Lupin only admits that what appears to be a copy of the '073 patent is attached as Exhibit A to the complaint and the face of the '073 patent speaks for itself. Lupin denies that the PTO duly and legally issued the '073 patent.

Complaint Paragraph 16: The '987 patent was duly and legally issued by the PTO on December 31, 2002 for an invention entitled "Sertraline Hydrochloride Polymorphs." A copy of the '987 patent is attached as Exhibit B.

Answer: With respect to paragraph 16 of the complaint, Lupin only admits that what appears to be a copy of the '987 patent is attached as Exhibit B to the complaint and the face of

the '987 patent speaks for itself. Lupin denies that the PTO duly and legally issued the '987 patent.

Complaint Paragraph 17: Both the '073 patent and the '987 patent claim, inter alia, processes for preparation of sertraline hydrochloride Form V.

Answer: With respect to paragraph 17 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in its present form, but to the extent Lupin understands said allegations and without waiver of the foregoing, Lupin admits only that claim 1 of the '073 patent concerns a process for making sertraline hydrochloride Form V and that claim 1 of the '987 patent concerns a process for making sertraline hydrochloride Form V. Lupin denies the remaining allegations in paragraph 17.

Complaint Paragraph 18: The '721 patent was duly and legally issued by the PTO on December 17, 2002 for an invention entitled "Sertraline Hydrochloride Form II and Methods for the Preparation Thereof." A copy of the '721 patent is attached as Exhibit C.

Answer: With respect to paragraph 18 of the complaint, Lupin only admits that what appears to be a copy of the '721 patent is attached as Exhibit C to the complaint and the face of the '721 patent speaks for itself. Lupin denies that the PTO duly and legally issued the '721 patent.

Complaint Paragraph 19: The '340 patent was duly and legally issued by the PTO on May 24, 2005 for an invention entitled "Processes for Preparation of Polymorphic Form II of Sertraline Hydrochloride." A copy of the '340 patent is attached as Exhibit D.

Answer: With respect to paragraph 19 of the complaint, Lupin only admits that what appears to be a copy of the '340 patent is attached as Exhibit D to the complaint and the face of

the '340 patent speaks for itself. Lupin denies that the PTO duly and legally issued the '340 patent.

Complaint Paragraph 20: The '721 and '340 patents claim, inter alia, processes for the preparation of sertraline hydrochloride Form II.

Answer: With respect to paragraph 20 of the complaint, the allegations therein are unclear and nonspecific and Lupin cannot fairly respond to same in its present form but to the extent Lupin understands said allegations and without waiver of the foregoing, Lupin admits only that claim 1 of the '721 patent concerns a process for making sertraline hydrochloride Form II and that claim 1 of the '340 patent concerns a process for the preparation of sertraline hydrochloride Form II. Lupin denies the remaining allegations in paragraph 20.

Complaint Paragraph 21: Sertraline hydrochloride is a pharmaceutical compound useful in the treatment of depression. It is the active pharmaceutical ingredient ("API") in the product sold by Pfizer Inc. under the trade name ZOLOFT. Teva USA sells generic sertraline hydrochloride tablets in the United States that are manufactured by Teva Ltd.

Answer: With respect to paragraph 21, Lupin admits that sertraline hydrochloride is a pharmaceutical compound useful in the treatment of depression. Lupin also admits that sertraline hydrochloride is the active ingredient in the product sold by Pfizer Inc. under the trade name ZOLOFT. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 21, and therefore denies them.

Complaint Paragraph 22: Pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (1994) ("the Act"), Teva USA filed Abbreviated New Drug Application ("ANDA") No. 76-465 with the United States Food & Drug Administration ("FDA") for permission to market its generic sertraline hydrochloride tablets in the United States.

Answer: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22, and therefore denies them.

Complaint Paragraph 23: Ivax Pharmaceuticals, Inc. ("Ivax"), a separate wholly-owned subsidiary of Teva Ltd., filed ANDA No. 75-719 with the FDA, also seeking permission to market generic sertraline hydrochloride tablets in the United States.

Answer: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 23, and therefore denies them.

Complaint Paragraph 24: Ivax's ANDA was approved on June 30, 2006. Under § 355(j) of the Act, Ivax obtained a limited period of exclusivity from the FDA for its generic sertraline products in the United States. Pursuant to this exclusivity, the FDA will not approve any other ANDA for generic sertraline hydrochloride tablets for a period of 180 days from the date Ivax first commercially marketed a product under its ANDA. This exclusivity period expires on February 6, 2007, i.e., the FDA may grant final approval to other ANDA holders beginning on February 7, 2007.

Answer: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24, and therefore denies them.

Complaint Paragraph 25: Ivax has selectively waived its exclusivity period with respect to Teva USA's ANDA No. 76-465. Following this selective waiver, the FDA granted final approval to Teva's ANDA on August 11, 2006.

Answer: Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 25, and therefore denies them.



Complaint Paragraph 26: On information and belief, Defendants have filed ANDA No. 77-670 with the FDA, seeking permission to market generic sertraline hydrochloride tablets in competition with Plaintiffs.

Answer: Lupin admits the allegations in paragraph 26.

Complaint Paragraph 27: On information and belief, the FDA has tentatively approved Defendants' ANDA, and will issue final approval upon the expiration of Ivax's exclusivity period.

Answer: Lupin admits the allegations in paragraph 27, but states that the FDA has now finally approved ANDA No. 77-670.

Complaint Paragraph 28: On information and belief, Defendants plan and intend to import, manufacture, use, sell and/or offer to sell in the United States their sertraline hydrochloride tablets immediately upon receiving final FDA approval. On information and belief, Defendants plan and intend to engage in these activities prior to the expiration of the patents in suit.

Answer: With respect to paragraph 28, Lupin admits that it intends to import, offer, and sell sertraline hydrochloride tablets after final FDA approval and before the patents in suit expire. Lupin denies the remaining allegations in paragraph 28.

Complaint Paragraph 29: On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendants' plans and intentions to import, manufacture, use, sell and/or offer to sell in the United States their sertraline hydrochloride tablets constitute imminent, threatened acts of infringement under 35 U.S.C. § 271(g), which give rise to an actual controversy over which this Court may exercise jurisdiction.

Answer: Lupin denies the allegations in paragraph 29.

Complaint Paragraph 30: On information and belief, the sertraline hydrochloride API contained in Defendants' tablets is or will be Form II or Form V. On information and belief, sertraline hydrochloride Forms I, II and V are the crystalline forms that are most likely to be used in a pharmaceutical tablet. On information and belief, Form I is claimed by an unexpired United States patent assigned to Pfizer Inc., and thus it is unlikely that Defendants will attempt to market products containing that polymorph.

Answer: With respect to paragraph 30, Lupin admits (a) that its sertraline hydrochloride tablets include as the active ingredient sertraline hydrochloride Form II and (b) that Pfizer Inc. is assigned an unexpired patent covering sertraline hydrochloride Form I. Lupin denies the remaining allegations in paragraph 30.

Complaint Paragraph 31: On information and belief, Plaintiffs are not aware of any commercially viable process to manufacture Form V sertraline hydrochloride that is not covered by one or more claims of the '987 patent and/or the '073 patent. Thus, on information and belief, there is a substantial likelihood that the sertraline hydrochloride API in Defendants' tablets, if Form V, is or will be made by a process that infringes one or more claims of the '987 patent and/or the '073 patent.

Answer: With respect to paragraph 31, Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies them, but avers that its sertraline hydrochloride tablets do not include as the active ingredient sertraline hydrochloride Form V.

Complaint Paragraph 32: On information and belief, given the scope of Teva Ltd.'s patent rights to methods of making Form II, there is a substantial likelihood that the sertraline

hydrochloride API in Defendants' tablets, if Form II, is or will be made by a process that infringes one or more claims of the '721 patent and/or the '340 patent.

Answer: Lupin denies the allegations in paragraph 32.

Complaint Paragraph 33: Plaintiffs have made a reasonable effort to determine the process by which the sertraline hydrochloride API in Defendants' tablets is or will be made. Currently, Plaintiffs are unable to obtain from a public source samples of Defendants' tablets or API, or any information regarding the method used to manufacture the API. On November 30, 2006, Teva Ltd. notified Lupin Pharmaceuticals, Inc. of the existence of the patents in suit and requested a description of the manufacturing process for the API believed to be used in Defendants' tablets, and a sample of the API. In order to protect the confidentiality of Defendants' information, Teva Ltd. offered to enter into a confidentiality agreement.

Answer: Lupin denies the allegations in paragraph 33 but admits that Teva sent Lupin a letter dated November 30, 2006.

Complaint Paragraph 34: Defendants have not responded to Teva Ltd.'s requests for information relating to the manufacturing process for the API believed to be used in their tablets despite Teva Ltd.'s offer to review any material subject to a confidentiality agreement. Defendants also have not provided a sample of their API.

Answer: With respect to paragraph 34, Lupin admits only that it did not respond to Teva's November 30, 2006 letter and did not provide a sample of Lupin's API to Teva. Lupin denies the remaining allegations in paragraph 34.

Complaint Paragraph 35: On information and belief, even if Plaintiffs had been able to obtain samples of Defendants' tablets and/or API from a public source or from Defendants, Plaintiffs are not aware of any analytical technique or combination of techniques that could be

used to definitively establish that the sertraline hydrochloride in the tablets was made by one or more of the methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants' tablets infringe the patents in suit unless and until Defendants disclose to Plaintiffs the method by which the sertraline hydrochloride API contained therein is or will be made. Analysis of any samples, however, likely would have allowed Plaintiffs to determine their polymorphic form, which could have allowed Plaintiffs to narrow the number of asserted patents, or even have led to nonassertion of patents if neither Form II nor Form V were found.

Answer: Lupin denies the allegations in paragraph 35.

Complaint Paragraph 36: In the absence of a sufficient response from Defendants, Plaintiffs have no choice but to resort to judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present to the Court evidence that Defendants will infringe the patents in suit.

Answer: Lupin denies the allegations in paragraph 36.

Complaint Paragraph 37: On information and belief, Defendants' infringement will be willful and deliberate.

Answer: Lupin denies the allegations in paragraph 37.

Complaint Paragraph 38: As a direct and proximate consequence of the planned and intended infringement by Defendants, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury and damages for which they are entitled to relief.

Answer: Lupin denies the allegations in paragraph 38.

**COUNT I**  
**Declaratory Judgment of Patent Infringement**

Complaint Paragraph 39: The allegations of paragraphs 1 to 38 are incorporated by reference as if fully set forth herein.

Answer: Lupin's answers to the allegations of paragraphs 1 to 38 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 40: The importation, manufacture, use, sale and/or offer to sell by the Defendants of their sertraline hydrochloride tablets pursuant to ANDA No. 77-670 will infringe one or more claims of the '073, '987, '721 and/or '340 patents under 35 U.S.C. § 271.

Answer: Lupin denies the allegations in paragraph 40.

**DEFENSES**

Without any admission as to the burden of proof or as to any of the averments in the Complaint, Lupin sets forth the following defenses:

**First Defense**

The '073, '987, '721 and '340 patents' claims do not cover Lupin's sertraline hydrochloride tablets, or the active ingredient in those tablets, or the process used to make the active ingredient in those tablets. Thus, Lupin has not infringed and does not infringe any of the '073, '987, '721 and '340 patents by making, using, selling, offering for sale, marketing, or importing its sertraline hydrochloride tablets or the active ingredient in those tablets.

**Second Defense**

The '073, '987, '721 and '340 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

### **COUNTERCLAIM**

Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) by way of Counterclaim against Plaintiffs, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively “Teva”), state:

#### **The Parties**

1. Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

2. Lupin Limited is an Indian corporation with an address at Laxmi Towers, B Wing, Bandra Kurla Complex, Mumbai, 400 051, India.

3. On information and belief, Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

4. On information and belief, Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly owned subsidiary of Teva Ltd.

#### **Jurisdiction**

5. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Lupin seeks declaratory relief, i.e., a declaration that the patents in suit are not infringed and that they are invalid.

6. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

#### **Factual Background**

7. United States Patent No. 6,600,073 (“the ’073 patent”), entitled “Methods for Preparation of Sertraline Hydrochloride Polymorphs,” was issued on July 29, 2003.

8. United States Patent No. 6,500,987 (“the ’987 patent”), entitled “Sertraline Hydrochloride Polymorphs,” was issued on December 31, 2002.

9. United States Patent No. 6,495,721 (“the ’721 patent”), entitled “Sertraline Hydrochloride Form II and Methods for the Preparation Thereof,” was issued on December 17, 2002.

10. United States Patent No. 6,897,340 (“the ’340 patent”), entitled “Processes for Preparation of Polymorphic Form II of Sertraline Hydrochloride,” was issued on May 24, 2005.

11. Upon information and belief, the ’073 patent, the ’987 patent, the ’721 patent, and the ’340 patent are all assigned to Teva Pharmaceutical Industries Ltd.

12. The patents in suit concern various crystalline forms of sertraline hydrochloride and methods for making various crystalline forms of sertraline hydrochloride.

13. Lupin submitted Abbreviated New Drug Application (“ANDA”) No. 77-670 to the Food and Drug Administration (“FDA”) seeking approval to market tablets containing sertraline hydrochloride as the active ingredient.

14. The FDA has granted final approval to ANDA No. 77-670.

**First Count**  
**(Declaration of Noninfringement)**

15. Lupin repeats and realleges paragraphs 1 through 14 of the counterclaim.

16. Teva has asserted the ’073, ’987, ’721 and ’340 patents against Lupin. Teva maintains—and Lupin denies—that the ’073, ’987, ’721 and ’340 patents’ claims cover Lupin’s sertraline hydrochloride tablets, the active ingredient in those tablets, and/or the process used to make the active ingredient in those tablets.

17. The ’073, ’987, ’721 and ’340 patents’ claims do not cover Lupin’s sertraline hydrochloride tablets, or the active ingredient in those tablets, or the process used to make the

active ingredient in those tablets. Thus, Lupin has not infringed and does not infringe any of the '073, '987, '721 and '340 patents by making, using, selling, offering for sale, marketing, or importing its sertraline hydrochloride tablets or the active ingredient in those tablets.

18. There is a substantial controversy between Lupin and Teva having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the infringement of the '073, '987, '721 and '340 patents.

19. Lupin is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of its sertraline hydrochloride tablets, the active ingredient in those tablets, and the process used to make the active ingredient in those tablets does not infringe any of the '073, '987, '721 and '340 patents.

**Second Count**  
**(Declaration of Invalidity)**

20. Lupin repeats and realleges paragraphs 1 through 14 of the counterclaim.

21. The '073, '987, '721 and '340 patents and all their claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

22. Teva maintains—and Lupin denies—that the '073, '987, '721 and '340 patents are valid.

23. There is a substantial controversy between Lupin and Teva having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the validity of the '073, '987, '721 and '340 patents.

24. Lupin is entitled to a judicial declaration that the '073, '987, '721 and '340 patents are invalid.

WHEREFORE, Lupin demands judgment in its favor and against Teva as follows:



(a) Dismissing the complaint with prejudice and denying each request for relief made by Teva;

(b) Declaring the '073 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's sertraline hydrochloride tablets, the active ingredient in those tablets, and the process used to make the active ingredient in those tablets;

(c) Declaring the '987 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's sertraline hydrochloride tablets, the active ingredient in those tablets, and the process used to make the active ingredient in those tablets;

(d) Declaring the '721 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's sertraline hydrochloride tablets, the active ingredient in those tablets, and the process used to make the active ingredient in those tablets;

(e) Declaring the '340 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Lupin's sertraline hydrochloride tablets, the active ingredient in those tablets, and the process used to make the active ingredient in those tablets;

(f) Declaring the '073 patent and all its claims invalid;

(g) Declaring the '987 patent and all its claims invalid;

(h) Declaring the '721 patent and all its claims invalid;

(i) Declaring the '340 patent and all its claims invalid;

(j) Enjoining Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc., their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any plaintiff from threatening to assert or otherwise attempting to enforce any of the '073, '987, '721 and '340 patents against Lupin, its customers, suppliers, or anyone in privity with Lupin;

- (k) Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding Lupin its attorney fees;
- (l) Awarding Lupin its costs and expenses; and
- (m) Awarding Lupin such other and further relief as the Court deems just and proper.

Respectfully submitted,

**SAIBER SCHLESINGER SATZ & GOLDSTEIN, LLC**

*Attorneys for Defendants,  
Lupin Limited and Lupin Pharmaceuticals, Inc.*

Dated: March 2, 2007

By: /s/ Arnold B. Calmann  
Arnold B. Calmann, Esq.  
Jeffrey Soos, Esq.  
One Gateway Center, 13<sup>th</sup> Floor  
Newark, New Jersey 07102  
Telephone: (973) 622-3333  
Facsimile: (973) 622-3349

*Of Counsel:*  
Barry S. White, Esq.  
Steven M. Amundson, Esq.  
Dillon Kim, Esq.  
**FROMMER LAWRENCE & HAUG LLP**  
745 Fifth Avenue  
New York, New York 10151  
Telephone: (212) 588-0800  
Facsimile: (212) 588-0500